Where can I find more details about the study?

If you are interested in learning more about the study you can contact your local research team who will be able to answer any questions you may have and help you in determining whether you may be interested in participating.

RESEARCH TEAM CONTACT INFORMATION

Minneapolis VA Medical Center
One Veterans Drive
Minneapolis, MN 55417

Study Coordinator

John Belew, RN
612-467-4806

Local Site Investigators

Andrew Reinink, MD
At 612-467-4100

Participating Sites

- Minneapolis VA Medical Center, Minnesota

For more information visit:
http://clinicaltrials.gov
NCT03005379

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VA Cooperative Studies Program #2004

MATCH

Microbiota or Placebo after Antimicrobial Therapy for Recurrent C.difficile at Home

Clinical Research Study

For Veterans with recurrent *C. difficile* infection.

Sponsored by the VA Cooperative Studies Program, a Division of VA Research and Development

VA | U.S. Department of Veterans Affairs

What is a clinical trial?

A clinical trial is a scientific investigation in which people can help doctors find ways to treat disease and improve healthcare.

What is the MATCH study?

The goal of the this research study is help determine the best method for preventing recurrence of *C. difficile* infection (CDI).

The study will compare administration of via Fecal Microbiota Transplant (FMT), also known as 'stool transplant' vs. placebo.

The study will be conducted among veterans in the United States, and last approximately 3.5 years. Veterans enrolled in the study will participate for approximately 7 months .

Who can participate?

Veterans age 18 and older who have had one or more episodes of recurrent *C.difficile* infection; have had resolution or improvement of symptoms from the most recent CDI episode; enroll within 2 to 14 days after completion of antimicrobial therapy or 30 days after the onset of CDI (whichever is later); and are able to provide informed consent can participate. Veterans living anywhere in the United States are eligible to participate.

What are the study procedures?

The study will be thoroughly explained to you and you will have an opportunity to ask all of your questions. When you have a good understanding of the study and are interested in taking part, you will be asked to sign a consent form. You will then be "screened" to be sure you are right for the study and that the study is right for you. You will be randomly selected (like flipping a coin) to receive either Microbiota or Placebo.

Microbiota: Half the study participants will receive Fecal Microbiota Transplant (FMT) via oral capsule.

Placebo: Half the study participants will receive a placebo (sugar pill).

All Participants: All study participants will be followed via phone at days 2, 14, and 56 after capsule administration, via automated system on day 28 and 42, and once a month thereafter until the final phone follow-up at month 6.

What will it cost?

You will not be charged co-pays for the study treatment (as applicable). If you usually pay co-payments for VA care, you will continue to pay them for all clinical care visits and medications, which may include any future visits related to your participation in this study. Participants will receive a small stipend to cover the cost of their visits.

Why should I take part in this trial?

Participating in a clinical research study gives you a chance to play an active part in your own healthcare and help others. Or, you may agree to participate just so you can contribute to medical research, even though you may not receive any direct benefit from the research.

What if I change my mind?

You are free to withdraw from the study at any time without prejudicing your future medical treatment.

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